IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	)	Civil Action No. 06-222 (JJF)

PLAINTIFF WYETH'S REPLY TO THE FIRST AMENDED COUNTERCLAIMS OF DEFENDANT IMPAX LABORATORIES, INC.

Plaintiff Wyeth, for its Reply to the First Amended Answer, Affirmative Defenses, Counterclaims And Prayer For Relief Of Defendant Impax Laboratories, Inc. ("Impax's Amended Counterclaims")(D.I. 33), filed on August 16, 2006, hereby states as follows:

1. Responding to paragraph 49 of Impax's Amended Counterclaims, Wyeth reasserts and realleges paragraphs 1-43 of its Complaint (D.I. 1), and denies the allegations of paragraphs 44-48 of Impax's Amended Answer and Counterclaims.

2. Responding to paragraph 50 of Impax's Amended Counterclaims, Wyeth admits, on information and belief, that Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544 and another place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124. Wyeth lacks knowledge sufficient to form a belief as to the truth of the remaining allegations of paragraph 50 and, on that basis, denies the same.

3. Responding to paragraph 51 of Impax's Amended Counterclaims, Wyeth denies that "Wyeth, Inc." is its name. Wyeth admits that it is a corporation incorporated under the laws

of the State of Delaware, with its principal place of business in Madison, New Jersey. Wyeth denies the remaining allegations of paragraph 51.

4. Responding to paragraph 52 of Impax's Amended Counterclaims, Wyeth admits that this Court has subject matter jurisdiction over the counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies that Impax is entitled to any of the relief it seeks.

5. Responding to paragraph 53 of Impax's Amended Counterclaims, Wyeth admits that it has sued Impax for patent infringement in this Judicial District and that this Court has personal jurisdiction over Wyeth for purposes of the present litigation. In addition, Wyeth admits that venue is proper in this Court for purposes of the present litigation. Wyeth denies the remaining allegations of paragraph 53.

6. Responding to paragraph 54 of Impax's Amended Counterclaims, Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54 and, on that basis, denies the same.

7. Responding to paragraph 55 of Impax's Amended Counterclaims, Wyeth admits that it is an innovative, research-based, pharmaceutical company with a long history of pioneering developments in pharmaceuticals and biotechnology that have improved the lives of millions of people around the world. Wyeth admits that in 2005 it had over $18 billion dollars in revenue and over $3 billion dollars in net income.

Wyeth also admits that after undergoing a lengthy, costly, and uncertain research and development process to obtain FDA approval, Wyeth began selling an immediate release dosage form of venlafaxine hydrochloride under the brand name Effexor® in 1994 in the United States. Wyeth, however, recognized the shortcomings of immediate release Effexor® early on, and began working towards possible solutions to those shortcomings with the development of an

extended release product even before the immediate release Effexor® product was ever approved or sold.

After undergoing yet another lengthy, costly, and uncertain research and development process to obtain FDA approval for the extended release dosage form of venlafaxine hydrochloride that it developed, Wyeth began selling an extended release dosage form of venlafaxine hydrochloride under the brand name Effexor® XR in 1997 in the United States. Wyeth further admits that it still sells immediate release venlafaxine hydrochloride under the brand name Effexor® for the treatment of depression in the United States, but states that the sales of Effexor® are but a small fraction of the sales of Effexor® XR. Wyeth denies the remaining allegations of paragraph 55.

8. Responding to paragraph 56 of Impax's Amended Counterclaims, Wyeth admits that it owns U.S. Patent No. 4,535,186 ("the '186 patent"), which includes claims directed to the compound venlafaxine hydrochloride. Wyeth further admits that the United States Patent and Trademark Office ("PTO") extended the expiration date of the '186 patent from December 13, 2002 to December 13, 2007 pursuant to 35 U.S.C. § 156. In further recognition of Wyeth's additional pediatric clinical research, the FDA has extended the patent exclusivity period for the '186 patent to June 13, 2008. Wyeth denies the remaining allegations of paragraph 56.

9. Responding to paragraph 57 of Impax's Amended Counterclaims, Wyeth admits that on March 25, 1996, American Home Products Corporation filed provisional patent application No. 60/014,006 ("the '006 application"). Wyeth further admits that United States Patent Nos. 6,274,171 B1 ("'171 patent"), 6,403,120 B1("'120 patent"), and 6,419,958 B2 ("'958 patent") (collectively, "the patents-in-suit") were issued by the United States Patent and Trademark Office to inventors Deborah M. Sherman, John C. Clark, John U. Lamer, and Steven

A. White. Wyeth further admits that each of the patents-in-suit claim priority to the '006 application through a series of applications. Wyeth further admits that in 2002, American Home Products Corporation changed its name to Wyeth, which owns the patents-in-suit. Wyeth denies the remaining allegations of paragraph 57.

10. Wyeth admits that paragraph 58 of Impax's Amended Counterclaims accurately quotes a passage (with emphasis added by Impax) contained in the '006 application, as originally filed with the PTO, relating to extended release venlafaxine hydrochloride, the use of which is claimed in each of the patents-in-suit. Wyeth denies the remaining allegations of paragraph 58.

11. Responding to paragraph 59 of Impax's Amended Counterclaims, Wyeth admits that on May 16, 1996, Wyeth-Ayerst Laboratories submitted NDA No. 20-699 to the FDA. At that time, Wyeth-Ayerst Laboratories was a division of American Home Products Corporation. In 2002, American Home Products Corporation changed its name to Wyeth. Wyeth admits that Wyeth-Ayerst Laboratories submitted NDA No. 20-699 for the purpose of obtaining approval to market Effexor® XR (an extended release formulation of venlafaxine hydrochloride) in the United States. Wyeth denies the remaining allegations of paragraph 59.

12. Responding to paragraph 60 of Impax's Amended Counterclaims, Wyeth admits that NDA No. 20-699 as submitted on May 16, 1996 indicated that clinical studies "208-US" ("Study 208"), "209-US" ("Study 209") and "367-EU" ("Study 367") on Effexor® XR had been completed. Wyeth denies the remaining allegations of paragraph 60.

13. Responding to paragraph 61 of Impax's Amended Counterclaims, Wyeth admits that the cover letter to the May 16, 1996 submission of NDA No. 20-699 describes "*Protocol 600-B-208-US*" as a "double-blind, flexible-dose, twelve-week efficacy study of 75-150 mg venlafaxine ER, 75-150 mg Effexor, and placebo in outpatients with major depression." Wyeth

further admits that it sells an immediate release tablet formulation of venlafaxine hydrochloride under the brand name Effexor®. Wyeth denies the remaining allegations of paragraph 61.

14. Responding to paragraph 62 of Impax's Amended Counterclaims, Wyeth admits that the cover letter to the May 16, 1996 submission of NDA No. 20-699 describes "*Protocol 600-B-209-US*" as a "double-blind, flexible-dose, eight-week efficacy study of 75-225 mg venlafaxine ER and placebo in outpatients with major depression." Wyeth denies the remaining allegations of paragraph 62.

15. Responding to paragraph 63 of Impax's Amended Counterclaims, Wyeth admits that the cover letter to the May 16, 1996 submission of NDA No. 20-699 describes "*Protocol 600-B-367-UK*" as a "double-blind, fixed-dose, eight-week efficacy study of 75 and 150 mg venlafaxine ER, 20 mg Paxil, and placebo in outpatients with major depression." Wyeth denies the remaining allegations of paragraph 63.

16. Responding to paragraph 64 of Impax's Amended Counterclaims, Wyeth admits that Study 208, Study 209 and Study 367 comprise the "two eight-week and one 12 week clinical studies" referenced in the third sentence of the quotation from the '006 application in paragraph 58 of Impax's Amended Counterclaims. Wyeth denies the remaining allegations of paragraph 64.

17. Responding to paragraph 65 of Impax's Amended Counterclaims, Wyeth admits that patients in Study 208 received extended release venlafaxine, immediate release venlafaxine tablets, or placebo; patients in Study 209 received extended release venlafaxine or placebo; and patients in Study 367 received extended release venlafaxine, paroxetine, or placebo. Wyeth further admits that patients in Studies 209 and 367 did not receive immediate release venlafaxine hydrochloride tablets. Wyeth denies the remaining allegations of paragraph 65.

18. Wyeth denies the allegations of paragraph 66 of Impax's Amended Counterclaims. Responding further, Wyeth denies Impax's allegation that "the only study directly comparing the two formulations did not show the claimed statistical significance." Wyeth further states that during the prosecution of the patents-in-suit, Wyeth never represented to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®.

19. Responding to paragraph 67 of Impax's Amended Counterclaims, Wyeth admits that patients in Studies 209 and 367 did not receive immediate release venlafaxine hydrochloride tablets. Wyeth further states that during the prosecution of the patents-in-suit, Wyeth never represented to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®. Wyeth denies the remaining allegations of paragraph 67.

20. Wyeth denies the allegations of paragraph 68 of Impax's Amended Counterclaims.

21. Responding to paragraph 69 of Impax's Amended Counterclaims, Wyeth states that during the prosecution of the patents-in-suit, Wyeth never represented to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®. Wyeth denies the remaining allegations of paragraph 69 of Impax's Amended Counterclaims.

22. Wyeth denies the allegations of paragraph 70 of Impax's Amended Counterclaims.

23. Wyeth denies the allegations of paragraph 71 of Impax's Amended Counterclaims.

24. Responding to paragraph 72 of Impax's Amended Counterclaims, Wyeth admits that the current FDA-approved package insert for Effexor® XR does not contain a statement that Effexor® XR showed "a statistically significant improvement in nausea" over Effexor®. Wyeth further admits that the current FDA-approved package insert includes some information on immediate release Effexor®. Wyeth denies the remaining allegations of paragraph 72 of Impax's Amended Counterclaims.

25. Wyeth denies the allegations of paragraph 73 of Impax's Amended Counterclaims.

26. Wyeth denies the allegations of paragraph 74 of Impax's Amended Counterclaims.

27. Wyeth denies the allegations of paragraph 75 of Impax's Amended Counterclaims.

28. Responding to paragraph 76 of Impax's Amended Counterclaims, Wyeth admits that the Cunningham article states that it was authored by Lynn A. Cunningham, M.D. In addition, the words, "for the Venlafaxine XR 208 Study Group" appear after her name on the first page of the article. Wyeth further admits that the Cunningham article describes certain results from Study 208. Wyeth further admits that the Cunningham article states that "[t]his study was supported by Wyeth-Ayerst Research, Radnor, Pennsylvania." Wyeth further admits that at the time of the Cunningham article Wyeth-Ayerst Research was affiliated with American Home Products Corporation. Wyeth denies the remaining allegations of paragraph 76 of Impax's Amended Counterclaims.

29. Wyeth denies the allegations of paragraph 77 of Impax's Amended Counterclaims.

30. Responding to paragraph 78 of Impax's Amended Counterclaims, Wyeth admits that the Cunningham article discusses certain results from Study 208. In addition, Wyeth admits that paragraph 78 of Impax's Amended Counterclaims accurately quotes a sentence in the Cunningham article with the exception of a missing hyphen and the added bracketed material. Wyeth denies the remaining allegations of paragraph 78 of Impax's Amended Counterclaims.

31. Wyeth denies the allegations of paragraph 79 of Impax's Amended Counterclaims.

32. Wyeth denies the allegations of paragraph 80 of Impax's Amended Counterclaims.

33. Responding to paragraph 81 of Impax's Amended Counterclaims, Wyeth admits that the patents-in-suit were issued by the United States Patent and Trademark Office. Wyeth further admits that each of the patents-in-suit claim priority to the same provisional patent application No. 60/014,006, filed on March 25, 1996. Wyeth denies the remaining allegations of paragraph 81.

34. Responding to paragraph 82 of Impax's Amended Counterclaims, Wyeth admits that Wyeth obtained FDA approval for the extended release venlafaxine hydrochloride product Effexor® XR. While U.S. sales of Effexor® plateaued at about $225 million per year, U.S. sales of Effexor® XR have steadily increased to over $2 billion per year. The benefits of Effexor® XR as compared to Effexor® are reflected in the significant differences in market performance for those products and explain the commercial success of Effexor® XR. Wyeth denies the remaining allegations of paragraph 82.

35. Responding to paragraph 83 of Impax's Amended Counterclaims, Wyeth admits that Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA to obtain approval

to manufacture, use and sell an extended release venlafaxine hydrochloride dosage form. Wyeth denies that Teva's certification letter to Wyeth stated that the '171, '120 and '958 patents' method claims would not be infringed by Teva. In fact, Teva's certification letter to Wyeth did not dispute Teva's infringement of the method claims of the patents-in-suit. Wyeth further admits that Wyeth sued Teva for patent infringement in the United States District Court, District of New Jersey. Wyeth also admits that a Markman hearing was held in that litigation after extensive discovery and that the Court issued a Markman Order which was later vacated. A copy of the Court's Order vacating its own Markman Order is attached as Exhibit A. Wyeth admits that the litigation with Teva was settled and that certain terms of the settlement remain confidential. However, Wyeth states that the settlement agreement was provided to the judge in the New Jersey litigation with Teva as well as to the FTC. Wyeth denies the remaining allegations of paragraph 83.

36. Responding to paragraph 84 of Impax's Amended Counterclaims, based on pages 003138-40 (IMPAX0003706-08) of what Impax purports to be ANDA No. 78-057, microcrystalline cellulose is not listed as an ingredient of Impax's venlafaxine extended release formulation. Wyeth denies the remaining allegations of paragraph 84.

37. Responding to paragraph 85 of Impax's Amended Counterclaims, Wyeth reasserts and realleges paragraphs 1-36, above.

38. Responding to paragraph 86 of Impax's Amended Counterclaims, Wyeth admits that an actual controversy exists between Wyeth and Impax with respect to enforceability, infringement, and validity of the patents-in-suit. Wyeth states that the patents-in-suit are enforceable, valid, and infringed by Impax. Wyeth denies that Impax is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 86.

39. Wyeth admits the allegations of paragraph 87 of Impax's Amended Counterclaims.

40. Wyeth denies the allegations of paragraph 88 of Impax's Amended Counterclaims.

41. Wyeth denies the allegations of paragraph 89 of Impax's Amended Counterclaims.

42. Wyeth denies the allegations of paragraph 90 of Impax's Amended Counterclaims.

43. Wyeth denies the allegations of paragraph 91 of Impax's Amended Counterclaims.

44. Wyeth denies the allegations of paragraph 92 of Impax's Amended Counterclaims.

45. Wyeth denies the allegations of paragraph 93 of Impax's Amended Counterclaims.

46. Wyeth denies the allegations of paragraph 94 of Impax's Amended Counterclaims.

47. Wyeth denies the allegations of paragraph 95 of Impax's Amended Counterclaims.

48. Responding to paragraph 96 of Impax's Amended Counterclaims, Wyeth reasserts and realleges paragraphs 1-36, above.

49. Responding to paragraph 97 of Impax's Amended Counterclaims, Wyeth admits that an actual controversy exists between Wyeth and Impax with respect to enforceability, infringement, and validity of the patents-in-suit. Wyeth states that the patents-in-suit are

enforceable, valid, and infringed by Impax. Wyeth denies that Impax is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 97.

50. Responding to paragraph 98 of Impax's Amended Counterclaims, Wyeth admits that during the prosecution of the patents-in-suit, the inventors of the patents-in-suit and attorneys responsible for prosecuting the patents-in-suit had a duty of candor and good faith in dealing with the PTO, including a duty to disclose to the PTO all information known to that individual to be material to patentability. Wyeth denies the remaining allegations of paragraph 98 of Impax's Amended Counterclaims.

51. Wyeth denies the allegations of paragraph 99 of Impax's Amended Counterclaims.

52. Wyeth denies the allegations of paragraph 100 of Impax's Amended Counterclaims.

53. Wyeth denies the allegations of paragraph 101 of Impax's Amended Counterclaims.

54. Wyeth denies the allegations of paragraph 102 of Impax's Amended Counterclaims.

55. Wyeth denies the allegations of paragraph 103 of Impax's Amended Counterclaims.

56. Wyeth denies the allegations of paragraph 104 of Impax's Amended Counterclaims.

57. Wyeth denies that Impax is entitled to any of the relief it seeks.

PRAYER FOR RELIEF

WHEREFORE, Wyeth respectfully requests that this Court enter judgment against Impax and that the Court enter an Order:

(1) dismissing Impax's Amended Counterclaims with prejudice;

(2) granting Wyeth the relief it requests in its Complaint;

(3) awarding Wyeth its attorneys' fees and costs; and

(4) awarding Wyeth such further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld (#1014)

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August 30, 2006

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CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that on August 30, 2006, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on August 30, 2006 upon the following in the manner indicated:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No.: 03-1293 (WJM)

ORDER VACATING MARKMAN RULINGS

Having considered the parties Joint Motion to Vacate Markman Rulings, and as a result of the parties' having executed the Settlement and Release Agreement dated November 2, 2005, the Court hereby Orders that:

The September 6, 2005 Markman Opinion and Order, and the October 6, 2005, Letter Opinion and Order denying Wyeth's Request for Reconsideration of the Markman Opinion and Order, are hereby vacated.

SO ORDERED THIS 12th day of January, 2006

William J. Martini, U.S.D.J.